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Support for claim 41 can be found in the specification on page 7, lines 16-18.

Support for claim 42 can be found in the specification on page 7, lines 22-23.

These amendments raise no new issues and the Applicants respectfully request the entry of these amendments.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-3, 8-9, 12 and 14-15 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Machida et al. (U.S.P.N. 5,759,866) (Machida). Claims 1-3, 8-9, 12 and 14-15 have been canceled thereby rendering the rejections to these claims moot. Applicants discuss the newly added claims in view of the above referenced prior art.

Machida teaches a microfluidic device and an assay method using this device that utilizes porous material within one region of the microchannel and wherein the device has one sample entry/exit port.

The new claims now recite a microfluidic device with a microchannel that comprises multiple, spacially distinct regions upon which specific binding pairs are immobilized. The device also comprises one or more entry ports, one or more exit ports, fluid propelling components, a detector to detect the binding pairs and a recirculating arm to recirculate the samples back into the microchannel. A method for detecting a specific binding member in a test sample using this microfluidic device is also claimed.

As the Examiner is aware, a *prima facie* case of obviousness requires that the prior art

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references must teach or suggest all the claim limitations. See M.P.E.P. § 2142.

The cited reference does not teach recirculation of the sample nor does it teach multiple spatially distinct regions within the microchannel wherein the specific binding pairs are immobilized.

Hence, Machida does not teach all the claim limitations. Therefore, Applicants submit that claims are not anticipated and respectfully request the withdrawal of the rejections under 35 U.S.C. § 103 (a).

Claims 8-9 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Machida et al. (U.S.P.N. 5,759,866) (Machida) as applied to claims 1-3, 8-9, 12 and 14-15 and further in view of Hancock (U.S.P.N. 5,716,825) (Hancock). Claims 1-3, 8-9, 12 and 14-15 have been canceled thereby rendering the rejections to these claims moot. Applicants discuss the newly added claims in view of the above referenced prior art.

Machida and the claims in the present invention have been discussed above.

Hancock teaches a device comprising a microchannel that connects a sample receiving well to a reaction well that is maintained at controlled temperature and that permits movement of analytes and fluids automatically within the compartment.

As the Examiner is aware, to anticipate a claim under 103 (a), in the prior art references, there must be some suggestion or motivation to combine the reference teachings and the references must teach every limitation of the claim (M.P.E.P. § 2142).

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None of the cited references, taken alone or in combination, teach recirculation of the samples or multiple spatially distinct regions with immobilizing structures like hydrogel pads. Also, neither reference provides the motivation to combine the above cited references.

Hence, Machida and Hancock do not teach all the claim limitations. Therefore, Applicants submit that claims are not anticipated and respectfully request the withdrawal of the rejections under 35 U.S.C. § 103 (a).

Claims 5-7 and 21 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Machida et al. (U.S.P.N. 5,759,866) (Machida) as applied to claims 1-3, 8-9, 12 and 14-15 and further in view of Lofas et al. (1990), *Chem. Comm.*, pp 1526-1528 (Lofas). Claims 1-3, 8-9, 12, 14-15 and 21 have been canceled thereby rendering rejections to these claims moot. Applicants discuss the newly added claims in view of the above referenced prior art.

Machida and the current invention have been discussed before.

Lofas teaches the use of hydrogels for the immobilization of biospecific pairs like antigen-antibody pairs.

Again, none of the cited references, taken alone or in combination, teach recirculation of the samples or multiple spatially distinct regions with immobilizing structures like hydrogel pads. Also, neither reference provides the motivation to combine the above cited references.

Hence, Machida and Lofas do not teach all the claim limitations. Therefore, Applicants submit that claims are not anticipated and respectfully request the withdrawal of the rejections

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under 35 U.S.C. §103 (a).

Claim 13 is rejected under 35 U.S.C. § 103 (a) as being unpatentable over Machida et al. (U.S.P.N. 5,759,866) (Machida) as applied to claims 1-3, 8-9, 12 and further in view of Zanzucchi et al. (U.S.P.N. 5,585,069) (Zanzucchi). Claims 1-3, 8-9, 12 and 14-15 have been canceled thereby rendering rejections to these claims moot. Applicants discuss the newly added claims in view of the above referenced prior art.

Machida and the current invention have been discussed before.

Zanzucchi teaches a microfluidic system utilizing a plurality of wells connected by one or more channels for the testing or synthesis of samples. The parallel modules run a plurality of tests in parallel. Zanzucchi teaches monitoring and controlling the flow of fluids in the array but does not teach recirculation of fluids or the use of spatially distinct regions within the microchannel for immobilizing binding pairs.

Even when Zanzucchi is combined with Machida, the combination does not teach recirculation of the samples nor does it teach multiple spatially distinct regions within the microchannel comprising a plurality of immobilizing structures like hydrogel pads. In addition, neither reference provides the motivation to combine the above cited references.

Hence, Machida and Zanzucchi do not teach all the claim limitations. Therefore, Applicants submit that claims are not anticipated and respectfully request the withdrawal of the rejections under 35 U.S.C. §103 (a).

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Applicants believe that every issue under Section 103(a) has been addressed, and respectfully request the withdrawal of the rejections.


On the basis of the amendments and remarks presented herein, Applicants believe that Claims 21-44 are patentable and respectfully request allowance of the pending claims.

Please direct any calls in connection with this application to the undersigned at (415) 781-1989.

Respectfully submitted,

FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP

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Robin M. Silva (38,304)

Four Embarcadero Center, Suite 3400
San Francisco, CA 94111-4187
Telephone: (415) 781-1989
1047475